IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Stefan Dietmar Anker and Andrew Justin Stewart Coats

Serial No.: 09/807,558 Art Unit: 1647

Filed: July 17, 2001 Examiner: Fozia M. Hamud

For: *METHODS OF TREATMENT*

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

PETITION UNDER 37 C.F.R. § 1.181 TO REVIEW THE EXAMINER'S DETERMINATION THAT DELETION OF MATERIAL FROM THE SPECIFICATION IS NEW MATTER

Sir:

Applicants' petition for review of the examiner's finding that Applicants' amendment to the specification to delete Examples 6 through 9 constitutes new matter by omission. Applicants submit that the deletion of Examples 6 through 9 does not constitute new matter prohibited by 35 U.S.C. § 132, and the objection should be withdrawn.

Statement of Facts

In a Final Office Action mailed on May 16, 2005, the Examiner refused to enter Applicants' amendment to the specification filed on February 10, 2005 because the amendments allegedly did not conform to 37 C.F.R. § 1.125(b) and (c) and because the deletion of Examples

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6 to 9 allegedly constituted new matter by omission. The Examiner concluded that the deletion of matter from the specification changed the content and substance of the specification such that "contemplation" was not the same.

Applicants submitted an amendment and response on September 16, 2005, amending, among other things, the specification.

On November 7, 2005, Applicants filed a Notice of Appeal.

On November 9, 2005, the Examiner mailed an Advisory Action refusing to enter the amendment of September 16, 2005. The Examiner indicated the amendment to the claims would be entered if submitted separately.

On November 21, 2005, Applicants submitted an amendment and response to amend the claims.

On January 19, 2006, the Examiner mailed a second Advisory Action indicating the amendments to the claims did not place the application in condition for allowance.

On April 14, 2006, Applicants submitted a Request for Continued Examination together with an Amendment and Response amending the specification as previously proposed and amending the claims.

On June 29, 2006, the Examiner mailed an Office Action entering the amendment filed on April 14, 2006. In the Office Action, the Examiner objected to the specification under 35 U.S.C. § 132 on the basis that the deletion of Examples 6-9 allegedly constitutes new matter by omission.

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Legal Standard

37 C.F.R. § 1.121(f) provides that "[n]o amendment may add new matter to the disclosure of an application." The prohibition of adding new matter to the specification is also codified at 35 U.S.C. § 132 which provides:

(a) Whenever, on examination, any claim for a patent is rejected, or any objection or requirement made, the Director shall notify the applicant thereof, stating the reasons for such rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application; and if after receiving such notice, the applicant persists in his claim for a patent, with or without amendment, the application shall be reexamined. No amendment shall introduce new matter into the disclosure of the invention.

The Court of Appeals for the Federal Circuit has held that, "The written description requirement and its corollary, the new matter prohibition of 35 U.S.C. § 132, both serve to ensure that the patent applicant was in full possession of the claimed subject matter on the application filing date". *TurboCare Div. of Demag Delaval Turbomachinery Corp. v. General Elec. Co.*, 264 F.3d 1111, 1118, 60 U.S.P.Q.2d (BNA) 1017, 1022; (Fed. Cir. 2001). See also *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 981 (Fed. Cir. 2002). 35 U.S.C. § 132(a) should be employed as a basis for objection to amendments to the abstract, specification, or drawings *attempting to add new disclosure* to that originally disclosed on filing. MPEP § 706.03(o)(emphasis added).

An objection and requirement to delete new matter by the examiner is subject to supervisory review by petition under 37 CFR § 1.181. MPEP § 2163.06.

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Analysis

In the June 29, 2006 Office Action, the Examiner objected to the deletion of Examples 6 to 9 as new matter because the "specification is not of the same scope [as originally filed]" (Office Action, page 3). The Examiner reasoned that the omission substantially changed the specification from the originally filed specification, and therefore is new matter by omission. Apart from citing 35 U.S.C. § 132, the Examiner did not provide any rule or case law to support the assertion that the deletion of Examples from the specification constitutes new matter.

The Examiner applied the wrong standard for determining whether new matter is introduced by deleting examples.

In the Advisory Action dated January 19, 2006, the Examiner cited to MPEP § 706.03(o) and 1411.02, arguing that the omission of a feature can be new matter. MPEP Section 706.03(o) states "[n]ew matter includes not only the addition of wholly unsupported subject matter, but may also include adding specific percentages or compounds after a broader original disclosure, or even the omission of a step **from a method**." This is clearly not the case in the present application. MPEP section 1411.02 is drawn to introduction of new matter in reissue applications. This is not a reissue application. Specifically, MPEP section 1411.02 states that in a reissue application "[n]ote that new matter may exist by virtue of the omission of a feature or of a step in a method. See *United States Industrial Chemicals, Inc. v. Carbide & Carbon Chemicals Corp.*, 315 U.S. 668, 53 USPQ 6 (1942)." This clearly refers to instances where omission of a feature or step may broaden the disclosure and thus be considered new matter. "This Court has uniformly held that the omission from a reissue patent of one of the steps or

elements prescribed in the original, thus broadening the claims to cover a new and different combination, renders the reissue void, even though the result attained is the same as that brought about by following the process claimed in the original patent." *U. S. Industrial Chemicals, Inc. v. Carbide & Carbon Chemicals Corp.*, 315 U.S. 668, 678 (U.S. 1942). Again, this is clearly not the case in the present application.

In the Office Action mailed on June 29, 2006, the Examiner remarks that although the deletion of Examples 6-9 is not an omission of step of a method, the deletion substantially changes the specification from the originally filed specification. The Examiner is applying the wrong standard for determining whether the specification complies with section 132.

The amended specification complies with section 132 as construed by the Federal Circuit.

As noted above the Federal Circuit has held the purpose of section 132 is to ensure that the applicant has possession of the claimed subject matter when the application was filed. The deletion of Examples 6 to 9 does not call into question whether or not the Applicants were in possession of the claimed subject matter. Indeed, the Examiner has not rejected a single claim based on a lack of written description in the specification due to the deletion of Examples 6 to 9. The amended specification complies with section 132 as construed by the Federal Circuit. The deletion of Examples 6-9 does not broaden the disclosure, and the examiner does not explain how the deletion could broaden the specification. Therefore, the objection to the specification should be withdrawn.

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Conclusion

For the foregoing reasons, Applicants request that this petition be granted and the

objection to the specification be withdrawn. The Commissioner is authorized to charge the fee

for this petition, if any, to Deposit Account No. 50-3129. It is believed that no additional fees

are required; however, the Commissioner is authorized to charge any additional fee or credit any

overpayment to Deposit Account No. 50-3129.

Respectfully submitted,

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